REMARKS

Claims 1-6, 11-29, 31-32 and 34-55 were pending in the present application. Claims 1, 26, 34 and 40 were amended and claims 13 and 45 were canceled without prejudice to or disclaimer of the subject matter therein. Support for the amendments may be found at least in the originally filed claims and paragraph [0034] of the application. Claims 1-6, 11, 12, 14-29, 31-32, 34-44 and 46-55 are now pending.

Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

I. Claims 1-6, 11-23, 25, 27, 34-39 And 41-55 Would Not Have Been Obvious Over The Art

Claims 1-6, 11-23, 25, 27, 34-39 and 41-55[1] were rejected under 35 U.S.C. § 103(a) as being unpatentable over Clark et al., U.S. Patent No. 5,259,835 (hereinafter "Clark"), in view of Ballance et al., U.S. Patent No. 6,439,789 (hereinafter "Ballance") further in view of MacDonald et al., U.S. Patent Application No. 2004/0142041 (hereinafter "MacDonald"), Zaffaroni, U.S. Patent No. 3,731,683, or Podell et al., U.S. Patent No. 5,620,702 (hereinafter "Podell") or Edenbaum et al., U.S. Patent No. 4,733,659 (hereinafter "Edenbaum"). Applicants respectfully traverse this rejection for at least the following reasons.

A. The Claims

Independent claim 1, as amended, is directed to a tissue bonding article comprising a flexible material, an adhesive substance applied covering substantially the entire bottom side of the flexible material and a polymerizable adhesive composition permeated throughout at least a portion of the flexible material wherein said polymerizable adhesive composition interacts with and/or solubilizes said adhesive substance. Claims 2-6, 11-12, 14-25, 27-29, 31-32 and 43-44 are directly or indirectly dependent on claim 1.

Independent claim 34, as amended is directed to a method of bonding tissue, comprising placing a flexible substrate over a section of tissue, wherein the flexible substrate comprises a flexible material and an adhesive substance applied covering substantially the entire bottom side of the flexible material; applying a polymerizable adhesive composition

[1] Claims 31 and 32 are not listed in the rejection, but are referred to during the explanation of the rejection in the Office Action. Claim 55 is rejected but is dependent on claim 40, not rejected.

over and substantially covering at least a portion of the flexible substrate, wherein said polymerizable adhesive composition interacts with and/or solubilizes said adhesive substance; and allowing the polymerizable adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to the tissue. Claims 35-39, 41 and 42 are directly or indirectly dependent on claim 34.

Regarding claims 1 and 34, and as described in the specification, the adhesive can be located on substantially an entire surface of the flexible substrate. When prepared in this manner, the adhesive substance can be coated to cover substantially the entire surface in a continuous coating or layer. Where the adhesive substance covers substantially an entire face of the flexible material, the polymerizable adhesive composition may interact with and/or solubilize the adhesive substances. Thus, the polymerizable adhesive composition is able to replace the adhesive substance as the primary means of attaching the composite structure to the underlying substrate (application site, such as tissue or wound). This can occur, for example, either by the polymerizable adhesive composition solubilizing the adhesive substance, or by the polymerizable adhesive composition being able to bond the flexible material to the underlying substrate through gaps or voids either pre-existing or created in the adhesive substance layer. *Paragraph [0060].*

Independent claim 46 is directed to a tissue bonding article, comprising a flexible material having a top side and a bottom side; an adhesive substance applied over at least a portion of the bottom side of said flexible material; and a polymerizable adhesive composition applied to the entire top side of said flexible material and permeated throughout at least a portion of said flexible material. Claims 47-53 are directly or indirectly dependent on claim 46.

Independent claim 54 defines a method of bonding tissue, comprising placing a flexible substrate over a section of tissue, wherein said flexible substrate comprises a flexible material having a top side and a bottom side, and an adhesive substance applied over at least a portion of the bottom side of said flexible material; applying a polymerizable adhesive composition to and substantially covering the entire top side of the flexible material; and allowing the polymerizable adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to said tissue.

With regard to claims 46 and 54, and as explained in the present specification, the polymerizable adhesive composition is preferably applied over an entire surface of the flexible substrate.

> That is, while the flexible substrate may provide some wicking, flowing, or capillary movement of the polymerizable adhesive composition within the bulk material of the flexible substrate, such wicking or capillary movement is minimal, and is not intended to provide complete coverage of the polymerizable adhesive composition over the flexible substrate. Thus, for example, it will generally not be possible to apply one or two drops of the polymerizable adhesive composition to the flexible substrate, and expect the polymerizable adhesive composition to completely cover the flexible substrate (unless, of course, the flexible substrate is such a small size that the drops substantially cover the surface). Rather, in embodiments of the present invention, the polymerizable adhesive composition is applied by dabbing, brushing, rolling, painting, swabbing or the like, the polymerizable adhesive composition onto the flexible substrate.

Specification, paragraph [0076].

B. <u>The Cited Art</u>

Clark describes a wound closure device which employs a porous bonding member which receives a flowable adhesive which may be a cyanoacrylate. According to Clark, a flowable, fast setting, high strength adhesive is introduced into the bonding pad to bond the pad to the skin at opposite wound margins. *Column 1, lines 44-48.*

Ballance is directed to polymerizable 1,1-disubstituted ethylene monomer formulation applicators, applicator tips and applicator kits. The monomer may be surrounded by a container that may be engaged with an applicator tip. The applicator tip may have an internal cavity defined in an applicator tip body and a porous material member may be connected to the applicator tip body to be in fluid communication with the internal cavity. Bioactive agents, viscosity modifiers, initiators, inhibitors and/or stabilizers may be added to the applicator, preferably in or on the porous material member. *Abstract.*

MacDonald is directed to a triggerable delivery system for pharmaceutical and nutritional compounds. In a specific embodiment, carrier particles including pharmaceutical compounds can be applied to a topical bandage. The delivery device described and shown in FIG. 1 includes an adhesive layer 72 for affixing the device to the skin of the patient. The adhesive layer may cover the entire lower surface of the transdermal delivery device, or only a peripheral portion of the lower surface, so as not to interfere with the passage of active ingredients across the skin of the consumer. *Paragraph [0054].*

Zaffaroni relates to a bandage for the controlled metering of topical drugs to the skin. The bandage is a laminate of (1) a backing member defining one face surface of the bandage,

(2) a pressure-sensitive adhesive adapted for contact with the skin or mucosa, the external surface of the pressure-sensitive adhesive defining the other face surface of the bandage, and disposed between the face surfaces defined by (1) and (2); (3) at least one reservoir comprised of a topically active drug formulation confined within a wall member, the wall member being formed from drug release rate controlling material to continuously meter the flow of drug from the reservoir to the skin or mucosa at a controlled and predetermined rate over a prolonged period of time. *Column 2, lines 23-37.* FIG. 1 illustrates an adhesive tape including a backing member 11 bearing a pressure-sensitive adhesive coating 12 on one surface thereof. Adhesive coating 12 has uniformly distributed therethrough microcapsules 13 of topically active agent encapsulated with a material permeable to passage of the drug. *Column 3, lines 51-57.*

Podell describes, *inter alia*, adhesive bandages made from a laminate structure of flexible rubber, a hydrophilic hydrogel polymer bonded to one side of the flexible rubber, and an adhesive bonded to the hydrophilic hydrogel polymer. *Abstract.* The adhesive may be placed around the entire circumference of the adhesive bandage leaving a central area which has the hydrogel polymer or medicament exposed, or the adhesive may be placed on two sections of the bandage with a middle section separating the two sections having the hydrogel polymer or medicament exposed, or the adhesive may cover the entire area of the bandage to cover the wound area to which it is applied. This provides tension and serves to draw the opposed skin surfaces adjacent a wounded area together to close the wound area. *Column 5, lines 38-49.*

Edenbaum is directed to a foam bandage and process for preparing the bandage including coating the entire surface of one side of a foam sheet or strip with a layer of porous pressure sensitive adhesive, covering the side of the laminate intended for wound contact in entirety with a suitable release liner and heat compressing the laminate except in a central area preselected to serve as the pad. *Column 2, lines 47-52.*

C. Argument

The framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 requires determining the scope and content of the prior art, ascertaining the differences between the claimed invention and the prior art and resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). According

to the Office Action, the cited art in combination would have made the invention as defined in the rejected claims obvious. Applicants disagree for the following reasons.

1. Claims 1 and 34

The USPTO has issued Examination Guidelines for determining obviousness under 35 U.S.C. § 103 in view of the Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (2007). None of the examination guidelines are believed to support the combination made by the examiner. According to the Office Action, Clark does not disclose the adhesive covering substantially the entire bottom side of the flexible material. *Office Action mailed July 27, 2007, page 6.* Applicants agree. However, the Office Action then states that with regard to claims 1 and 34, *inter alia*, MacDonald, Zaffaroni, Podell and Edenbaum teach an adhesive substance covering substantially the entire bottom surface of a bandage. *Office Action mailed July 27, 2007, page 7.* The Office Action then states:

> Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark's article to include an adhesive covering the entire bottom side of the flexible material. Such a modification would ease manufacturing and would secure the bandage to the entire surface to which it is being applied. One having ordinary skill in the art would expect the increased adhesive area would improve adhesion.

Office Action mailed July 27, 2007, pages 7-8. Applicants disagree.

Clark is directed to wound closure means wherein a skin contact adhesive may be used for temporarily apposing the edges of a wound. *Column 1, lines 50-51.* The application of the skin contact adhesive is shown in the figures of Clark at, for example, element 40 in FIG. 2. As shown in FIG. 2 and described in the specification:

> The wound closure device 30 includes means for holding the wound in apposed position and holding the bonding pad 36 in place during the time the adhesive bond between the bonding pad and the skin is being formed. In this regard, the intermediate portions 32b include a contact adhesive 40 on the underside thereof for at least temporarily holding the carrier member 32 onto the skin. Such contact adhesive may also be applied in a discontinuous fashion (indicated as portions 40a) to the skin contact side of the bonding pad 36 as shown in FIG. 2. **The discontinuous application of contact adhesive to the bonding pad 36 is desirable so that portions of the bonding pad wetted with the flowable adhesive are in contact with and can form a bond with the skin.**

Column 4, lines 27-41(emphasis added). Thus, Clark shows the use of skin contact adhesive on the edges of the bonding pad or applied in a discontinuous fashion. Clark does not

disclose or suggest the use of an adhesive substance applied over substantially the entire bottom side of flexible material as claimed. Moreover, Clark *teaches away* from using an adhesive substance applied over substantially the entire bottom side of flexible material since Clark specifically teaches that the discontinuous application of contact adhesive is desirable so that portions of the bonding pad wetted with the flowable adhesive are in contact with and can form a bond with the skin.

The rejected claims are directed to a structure wherein there is an adhesive substance applied covering substantially the entire bottom side of a flexible material and a polymerizable adhesive composition permeated throughout at least a portion of the flexible material. The polymerizable adhesive composition interacts with and/or solubilizes said adhesive substance. As detailed in the specification, the polymerizable adhesive composition is able to replace the adhesive substance as the primary means of attaching the composite structure to the underlying substrate.

The patents cited to allegedly show an adhesive substance covering substantially the entire bottom surface of a bandage do not describe or suggest a structure wherein the adhesive substance applied covering substantially the entire bottom side of a flexible material is used in conjunction with a polymerizable adhesive composition permeated throughout at least a portion of the flexible material such that the polymerizable adhesive composition ultimately provides the desired adhesion. Moreover, these patents do not disclose or suggest use of a polymerizable adhesive composition which interacts with and/or solubilizes said adhesive substance.

MacDonald is directed to carrier particles including pharmaceutical compounds that can be applied to a topical bandage. The adhesive element is not used in conjunction with a polymerizable adhesive composition permeated throughout at least a portion of the flexible material as defined in the rejected claims.

Zaffaroni relates to a bandage for the controlled metering of topical drugs to the skin. The adhesive of Zaffaroni is not used in conjunction with a polymerizable adhesive composition permeated throughout at least a portion of the flexible material as defined in the rejected claims.

Podell is directed to adhesive bandages made from a laminate structure of flexible rubber, a hydrophilic hydrogel polymer bonded to one side of the flexible rubber, and an adhesive bonded to the hydrophilic hydrogel polymer. The adhesive of Podell is not used in

conjunction with a polymerizable adhesive composition permeated throughout at least a portion of the flexible material as defined in the rejected claims.

Edenbaum is directed to a foam bandage. The adhesive of Edenbaum is not used in conjunction with a polymerizable adhesive composition permeated throughout at least a portion of the flexible material as defined in the rejected claims.

None of these patents provide the requisite teaching or suggestion which would have led one of ordinary skill in the art to make the combination alleged by the examiner. In view of the foregoing, Applicants respectfully request that the rejection be withdrawn.

2. Claims 46 and 54

With regard to claims 46 and 54, the Office Action alleges that Barley, Jr., U.S. Patent No. 5,653,769, teaches that an adhesive coating should be applied covering the entire surface of the skin. The Office Action additionally states that it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark's adhesive composition to be applied to the entire top surface of the flexible material. *Office Action mailed July 27, 2007, page 9.* Applicants disagree.

Barley is directed to application of a layer of cyanoacrylate polymer to skin area which will be in contact with an artificial device so as to form a flexible, waterproof polymer layer over the skin areas. The Barley patent does not disclose or suggest anything with regard to a polymerizable adhesive composition applied to the entire top side of a flexible material since Barley teaches placing the cyanoacrylate polymer on the skin itself. Barley specifically discloses, in the case of bandages, application made to that part of the skin surface where the adhesive of the bandage would otherwise contact the skin surface. *Column 7, lines 16-18.* Thus, the bandage of Barley is placed on top of the polymerized polymerizable adhesive composition.

None of the other cited patents provide a teaching or suggestion regarding polymerizable adhesive compositions applied to flexible material. The Clark patent discloses specific ports or locations for application of the flowable adhesive, not application thereof to the entire top side of a flexible material. *Column 4, lines 3-5, column 4, line 67 – column 5, line 2, and FIGS.* In view thereof, a combination of the art as alleged would not have made the invention as defined in claims 46 and 54 and dependent claims thereon obvious to one of ordinary skill in the art, and Applicants respectfully request that this rejection be withdrawn.

II. Claims 24, 26, 28 And 29 Would Not Have Been Obvious Over The Cited Art

Claims 24, 26, 28 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Clark et al., U.S. Patent No. 5,259,835 (hereinafter "Clark"), in view of Ballance et al., U.S. Patent No. 6,439,789 (hereinafter "Ballance") further in view of MacDonald et al., U.S. Patent Application No. 2004/0142041 (hereinafter "MacDonald"), or Zaffaroni, U.S. Patent No. 3,731,683, or Podell et al., U.S. Patent No. 5,620,702 (hereinafter "Podell") or Edenbaum et al., U.S. Patent No. 4,733,659 (hereinafter "Edenbaum"), and further in view of Porzilli, U.S. Patent No. 5,336,209. Applicants respectfully traverse this rejection for the following reasons.

Claim 24, 28 and 29 are dependent on claim 1. Clark, Ballance and the other cited patents are discussed above. Porzilli is directed to a protective wound bandage which allows for the ability to regulate and monitor oxygen flow to the injury site. Porzilli does not remedy the deficiencies of the combination of Clark and Ballance as described above since Porzilli does not disclose or suggest an adhesive substance applied over substantially the entire bottom side of a flexible material as claimed or a polymerizable adhesive composition that interacts with and/or solubilizes said adhesive substance. In view thereof, Applicants respectfully request that the rejection as to these claims be withdrawn.

Amended claim 26 is directed to a tissue bonding article, comprising a flexible material; an adhesive substance applied over at least a portion of a bottom side of the flexible material; and a polymerizable adhesive composition permeated throughout at least a portion of the flexible material, wherein the flexible material and the polymerizable adhesive composition form a composite structure that biodegrades over a set period of time.

Clark does not specifically disclose a flexible material and a polymerizable adhesive composition that form a composite structure that biodegrades over a set period of time. Ballance also does not disclose such a composite. Porzilli describes a dressing which can be manufactured from biodegradable materials if so desired, states that the skin release adhesive covering strip 24 would be manufactured in a biodegradable material in the preferred embodiment, and indicates that the tear tab cover 14 is, in a preferred embodiment, manufactured from a translucent, opaque or clear biodegradable material. *Column 2, lines 13-14, 35-36 and 66-68.* However, Porzilli does not disclose or suggest a material wherein there is a flexible material and a polymerizable adhesive composition which form a composite structure that biodegrades over a set period of time. Rather, Porzilli does not teach or suggest a biodegradable adhesive at all. In view thereof, none of the cited patents

discloses or suggests the tissue bonding article defined in claim 26 and Applicants respectfully request that this rejection be withdrawn.

III. Claim 40 Would Not Have Been Obvious Over The Cited Art

Claim 40 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Clark et al., U.S. Patent No. 5,259,835 (hereinafter "Clark"), in view of Ballance et al., U.S. Patent No. 6,439,789 (hereinafter "Ballance") further in view of MacDonald et al., U.S. Patent Application No. 2004/0142041 (hereinafter "MacDonald"), or Zaffaroni, U.S. Patent No. 3,731,683, or Podell et al., U.S. Patent No. 5,620,702 (hereinafter "Podell") or Edenbaum et al., U.S. Patent No. 4,733,659 (hereinafter "Edenbaum"), further in view of Vandruff, U.S. Patent Application 2002/0193721. Applicants respectfully traverse this rejection.

Claim 40 is directed to a method of bonding tissue. The method comprises placing a flexible substrate over a section of tissue wherein the section of tissue includes a wound to be closed and wherein the flexible substrate comprises a flexible material and an adhesive substance applied over at least a portion of a bottom side of the flexible material. The method further comprises applying a polymerizable adhesive composition over and substantially covering at least a portion of the flexible substrate, wherein the polymerizable adhesive composition interacts with and/or solubilizes said adhesive substance, and allowing the polymerizable adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to the tissue. The placing of the flexible substrate comprises fixing a first lengthwise end of the flexible substrate to the section of tissue on a first lengthwise end of the wound; approximating edges of the wound; and fixing a second lengthwise end of the flexible substrate to the section of tissue on a second lengthwise end of the wound opposite the first lengthwise end of the wound.

VanDruff is directed to a wound closure grid tape apparatus and method. VanDruff is meant to provide external stitches in about the same spacing as traditional stitches that are held in place by cross-members and adhesion to the skin. The "stitch" can be thought of as being planar to the skin and deriving its strength to hold the wound closed from adhesion by cross-members at right angles to the wound, and also from the circuits created by the cross-members of the grid structure rather than by looping into and through the skin surface. *Paragraph [0032]*. Clark describes wound apposition as taught therein as accomplished initially by means of a member extending across the wound and longer term, more permanent apposition is achieved by application of a flowable adhesive to a porous bonding member.

Column 10, lines 19-23. Since VanDruff was solving the problem with stitches by providing a grid which approximates the function of stitches and Clark uses a completely different system of a flowable adhesive system, placing a member across the wound, there would have been no motivation for modifying the wound closure system of Clark to apply the system as taught for the grid tape of VanDruff. In view thereof, Applicants respectfully request that the rejection be withdrawn.

IV. Conclusion

For the foregoing reasons, claims 1-6, 11, 12, 14-29, 31-32, 34-44 and 46-55 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

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